

17AD100 Nexgear Tango ankle joint

Fabricating an ankle-foot-orthosis and installing the modules

Technical information 5.2.4



1 Introduction

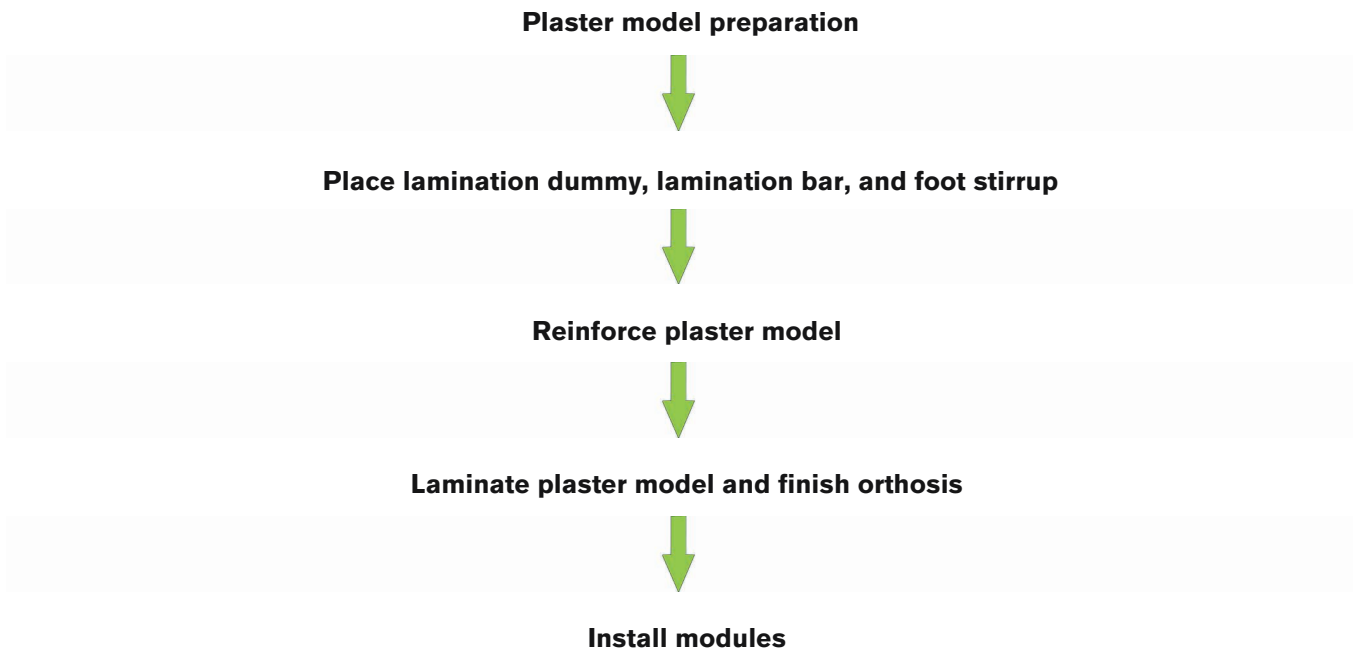
This technical information supports you in the fabrication of an ankle-foot-orthosis using lamination resin technology.

This document is directed to trained practitioners. It is a prerequisite that the qualified personnel are trained in the handling of the various materials, machines, and tools.

This technical information does not claim to be exhaustive. Reading this technical information does not substitute reading the instructions for use for all required products.

1.1 Flowchart

The entire process is shown in the following flowchart. All work steps described in this document are highlighted in bold.



2 Preparation

The following preparations must be made in order to work effectively:

- Collecting the tools and materials
- Performing preparatory work:
Fabricate a plaster model according to individual considerations.
Position the alignment adapter in the plaster model.
Apply the spacer material to the plaster model. (The fitting example shows the use of stockinette.)

Tools	
Designation	Reference number
Torque wrench 1 Nm to 25 Nm	710D20
Connecting element	710Y19
Torx wrench set	709S530
Torx bit set	710Y25
Nexgear Tango FIT KIT	17AD100A=FIT-KIT

Materials	
Designation	Reference number
Orthotic joint alignment fixture	743R6=*
PVC profile bars	17Y106
Perlon stockinette	623T3=*
PVA bag	99B81
Vulkollan elastic band	617B1
Carbon fiber cloth	616G12
Pastasil	85H11=*

Materials	
Designation	Reference number
Wax pen	633W8
Carbon-fiberglass webbing	616H10=*
Carbon fiber stockinette	616G15=*
Dacron felt	616G6
Quick-drying adhesive	636K11
Polyethylene adhesive tape	627B4
Plastaband	636K8
Double-sided PVC adhesive tape	616F10*
Spray adhesive	636K40
Isopropyl alcohol	634A58
C-Orthocryl lamination resin	617H55
Hardening powder	617P37=0.150
Talcum powder	639A1=1
Comfor Tex soft	623F109

3 Procedure

3.1 Plaster model preparation



Apply contact adhesive to the stockinette above the alignment adapter and allow it to become touch dry. Then remove the stockinette above the alignment adapter.

3.2 Positioning the lamination dummy, lamination bar, and foot stirrup



Mount the lamination bar in the lower part of the lamination dummy using 2 countersunk head screws.



Insert the foot stirrup into the lamination dummy cover, leaving the bearing bushing in the foot stirrup.



Slide the lamination dummy cover with the shoulder screw onto the lower part of the lamination dummy and mark the insertion zone on the bar and foot stirrup. Remove the bar and foot stirrup from the lamination dummy for machining.

NOTE: Do not machine the insertion zone of the bar and foot stirrup.

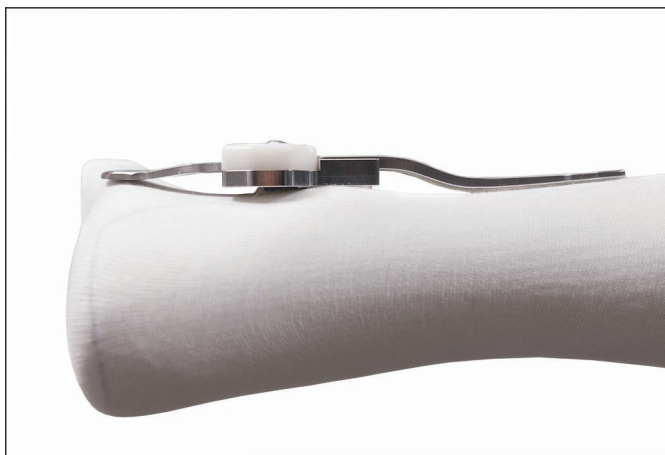


INFORMATION: The foot stirrup is secured in the neutral position by the design of the lamination dummy cover.

The neutral alignment of the foot stirrup permits the maximum dorsal or plantar range of motion in the orthosis joint.



Mold the foot stirrup and shorten it to the height of the outside edge of the foot. Screw the lamination dummy, lamination bar, and foot stirrup to the alignment insert with the shoulder screw.



Check the distance between the lamination bar/foot stirrup and the plaster model. The minimum distance must be approx. **2 to 3 mm**.



Deburr the bar and foot stirrup.



Reinforce the supporting surface with PVC profile material.

Heat the PVC profile material with a hot air gun and mold it into shape.



Apply the quick-drying adhesive to the surface to be glued to the lamination bar.



Glue the profile material to the lamination bar. Firmly press the gluing surfaces together.

3.3 Reinforcing

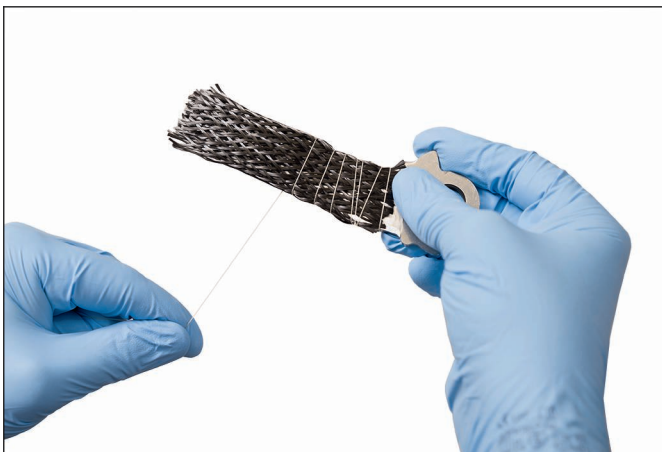
Bar and clamp



INFORMATION: Before reinforcing, roughen the bar and foot stirrup, and clean them using a degreasing cleaner.

Reinforce the foot stirrup with carbon fiber stockinette, letting the woven stockinette project approx. 5 cm beyond the foot stirrup.

Depending on the orthosis construction and the patient-specific requirements, pull 1 to 3 layers of woven stockinette over the foot stirrup.



Wrap the reinforcement with an unwaxed thread over the length of the foot stirrup to form fit the carbon fibres. Do **not** wrap the projecting woven stockinette. Reinforce the lamination bar and PVC profile material with woven stockinette and wrap with unwaxed thread.



Isolate the following components with wax in the area of the joints:

- Lamination dummy – lower part
- Bar/foot stirrup insertion zone
- Screws



Connect the isolated components to each other.

Orthosis



Use Plastaband to even out the sharp edges of the alignment insert.



Pull a soaked PVA bag over the plaster model.



Apply polyethylene adhesive tape over the alignment insert so the PVA bag does not tear later while screwing on the dummy.



Pull 1 layer of Perlon stockinette over the plaster model.



Apply contact adhesive to the stockinette above the alignment insert.
After the contact adhesive is touch dry, cut into the stockinette and expose the thread of the alignment insert.

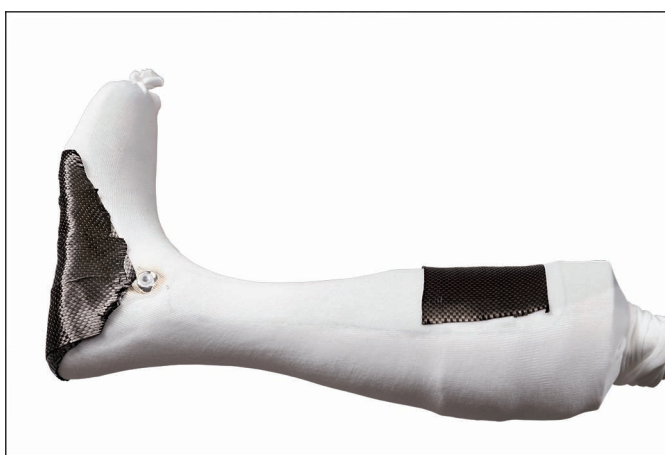


NOTE: Use as little adhesive tape or spray adhesive as possible, so that the fibers are thoroughly soaked during laminating.

Secure the carbon-fiberglass webbing to the Perlon stockinette with some double-sided adhesive tape or spray adhesive.

- Apply 1 layer of carbon-fiberglass webbing as full-surface reinforcement from the heel to the rollover edge in **a – p** direction.
- Apply 1 layer of carbon-fiberglass webbing as full-surface reinforcement from the heel to the rollover edge in **m – l** direction.

Reinforce to a maximum of **2 cm** below the ankle joint.



Use carbon-fiberglass webbing to reinforce the load-bearing areas of the orthosis encompassing the bar and support surface.



Apply 2 layers of carbon fiber woven stockinette (**5 cm** wide) in the lateral course of the bar.



Seal the connection zone above the alignment insert with Plastaband.

Cut the PVA foil above the thread.



Secure the reinforced components to the alignment insert using the shoulder screw.



Fan out the end of the carbon fiber stockinette.



Secure the fanned-out fibers to the reinforcement with carbon-fiberglass webbing.



Fan out the end of the carbon fiber stockinette and secure it with carbon-fiberglass webbing.



Fill the cavities between the plaster model and lamination bar/foot stirrup with Dacron felt.



Seal and level off all screws and protrusions on the plaster model with Pastasil.



Pull 1 layer of Perlon stockinette over the plaster model.



Apply 1 layer of carbon fiber cloth in the area of the tibia support surface.

Optional: Add reinforcement layers according to the patient's physical and functional requirements.



Optional: Fabricate a long foot component.

- Cut 2 layers of carbon fiber cloth to size (fiber orientation: **45°**).
- Position the carbon fiber cloth on the foot component.

INFORMATION: A flexible forefoot component is fabricated in this example.



Position carbon-fiberglass webbing from the heel to the rollover edge in **a - p** and **m - l** direction.



Apply carbon fiber stockinette (**5 cm** wide) in the lateral course of the bar.



Optional: Position 1 layer of Perlon stockinette and 1 layer of decorative fabric as the final layer or use 1 layer of carbon fiber cloth.

Prepare templates for this purpose. Transfer the blanks to the carbon fiber cloth and cut them out.



Secure the blanks on the model.



Then pull a thin stockinette over the model.

INFORMATION: The stockinette prevents the carbon fiber cloth layers from slipping while pulling the PVA bag over the model. In addition, the stockinette ensures that the lamination resin is distributed more quickly over the reinforcement.



Pull a soaked PVA bag over the model and tie it off on the vacuum tube.

3.4 Laminating and finishing



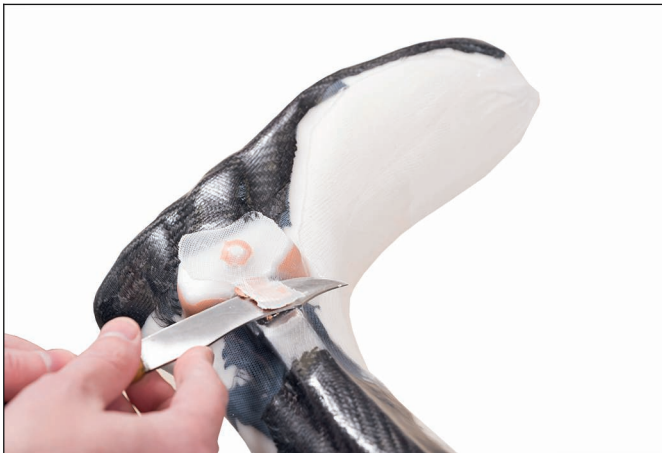
Turn on the vacuum and check the PVA bag to make sure there are no leaks.

Mix the lamination resin with the hardener.

NOTICE: To avoid overheating during curing, no more than 1.5% hardener should be added.

Carry out the lamination process.

After the laminate has fully hardened, mark the course of the edge on the orthosis.



Use a knife to expose the lamination dummy cover and the insertion zone of the lamination bar.

Remove the Pastasil from the screws.



Unscrew the screws from the lamination dummy and lamination bar.



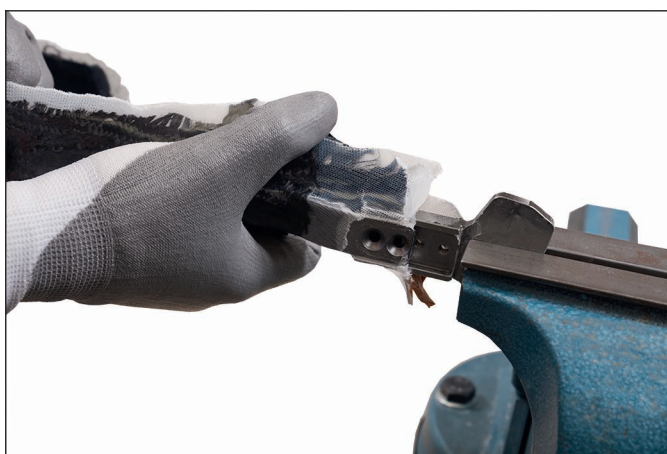
Remove the lamination dummy cover.



If the bearing bushing was removed with the lamination dummy cover, reinsert the bearing bushing into the foot stirrup.



Cut the orthosis open along the marked course of the edge using an oscillating saw and remove it from the plaster model.



NOTE: Use vice jaws to prevent damage to the product while clamping it in the vice.

Remove the lamination bar from the lamination dummy – lower part.



The shape of the lamination dummy produces the desired contour to enable the full range of motion of the orthosis joint without damaging the laminate.

3.5 Mounting the orthosis joint



Check the fit of the bearing bushing in the foot stirrup, or install the bearing bushing if it is missing.

INFORMATION: Mounting the lower leg component is not necessary to install the orthosis joint and individual modules.



Mount the orthosis joint with suitable axial washers:

- Position two axial washers of the same thickness medially and laterally on the foot stirrup and slide on the orthosis joint.
- Use thicker axial washers in case of play in the medial-lateral direction.



Insert the joint screw and joint nut, and tighten with a Torx wrench.

17AD100=	10	12	14	16	20
	T20	T20	T25	T30	T30
	3 Nm	3 Nm	5 Nm	8 Nm	8 Nm

3.6 Installing the Spring Module



Insert the threaded hole through the cover from above and screw it into the basic piece.



NOTE: Use vice jaws to prevent damage to the product while clamping it in the vice.

Place the mounting adapter onto the threaded hole and tighten it to the corresponding torque value.

17AD100=	10	12	14	16	20
17AD100A=MA-	10	12	14	20	20
	T20	T20	T25	T30	T30
	5 Nm	6 Nm	6 Nm	8 Nm	8 Nm



Insert the ball into the threaded hole.



Slide the spring into the spring guide housing and position it in the threaded hole.



Screw the setscrew into the threaded hole and tighten with a Torx wrench.

3.7 Installing the Stop Module



Insert the threaded hole through the cover from above and screw it into the basic piece so that the flattened side of the cover faces the basic piece.



NOTE: Use vice jaws to prevent damage to the product while clamping it in the vice.

Place the mounting adapter onto the threaded hole and tighten it to the corresponding torque value.

17AD100=	10	12	14	16	20
17AD100A=MA-	10	12	14	20	20
	T20	T20	T25	T30	T30
	5 Nm	6 Nm	6 Nm	8 Nm	8 Nm



Insert the stop sleeve into the threaded hole with the curve pointing towards the foot stirrup.



Screw the setscrew into the threaded hole and set it to the desired position.

3.8 Installing the Reaction Module



INFORMATION: The Nexgear Tango Reaction Module is delivered installed in the cover. Before the module can be installed in the orthosis joint, it has to be disassembled into the individual components.

Remove the cover cap from the spring bolt.



Press the module out of the cover.



Loosen the spring bolt and remove the spring dummy from the spring holder.



Remove the washer.



Unscrew the spring holder from the support element.



INFORMATION: The stop pin is provided with a thread lock and is therefore difficult to turn during adjustment. Avoid frequent adjustment of the stop pin to prevent damage to the thread lock. Optional: Use the 17AD100A=MA* mounting adapter as a lever extension of the Torx wrench.

Pull the spring plunger with the bearing sleeve and stop pin out of the support element.



Place the mounting adapter onto the support element and slide it through the cover.



Set the flattened side of the cover onto the base body.



Tighten the support element to the corresponding torque value.
Then remove the mounting adapter.

17AD100=	10	12	14	16	20
17AD100A=MA-	10	12	14	20	20
	T20	T20	T25	T30	T30
	5 Nm	6 Nm	6 Nm	8 Nm	8 Nm



Insert the spring plunger with the bearing sleeve and stop pin into the cover in the support element.



NOTE: To avoid damaging the fine thread, ensure proper alignment and smooth movement while screwing it in.

Use a Torx wrench to screw the spring holder into the internal thread of the support element.



Set the torque wrench with bit extension onto the spring holder and tighten it. Observe the specified torque.

17AD100=	10	12	14	16	20
	T25	T25	T25	T40	T40
	4 Nm	4 Nm	4 Nm	6 Nm	6 Nm



Position the washer on the spring holder.



Insert the spring dummy into the module.



Place the spring bolt on the module and tighten it with a Torx wrench until the spring dummy fits in the module with no play.

3.9 Reaction Module – static alignment



Put the orthosis on the patient.



Use the knee pivot point gauge to determine and mark the compromise pivot point according to Nietert on the knee joint.

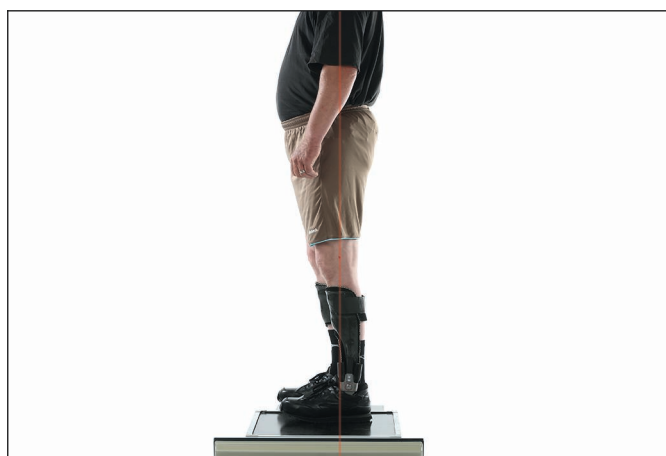


Pass the Torx wrench through the spring bolt to adjust the stop.



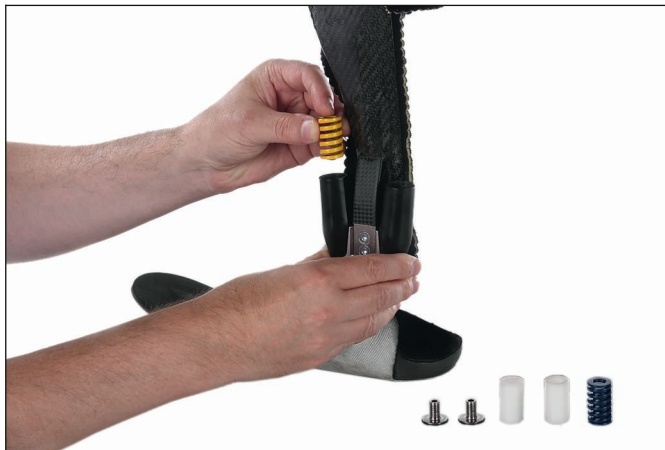
Relieve the lower leg by hand so that the stop pin can move easily in the thread.

INFORMATION: When using 2 Reaction Modules, adjust the orthosis joint until it no longer has any play in the a - p direction.



Check the static alignment of the orthosis using the L.A.S.A.R. Posture.

3.10 Reaction Module – dynamic alignment



For the dynamic trial fitting, unscrew the spring bolt with a Torx wrench and replace the spring dummy with the Reaction Spring.



Install the spring bolt.



Screw in the spring bolt flush with the cover using a Torx wrench.



Carrying out the dynamic trial fitting:

- Put the orthosis on the patient.
- Check the sagittal alignment of the orthosis on the patient using the L.A.S.A.R. Posture.
- Set the desired pretension of the Reaction Spring using the spring bolt.
- Have the patient walk while wearing the orthosis.

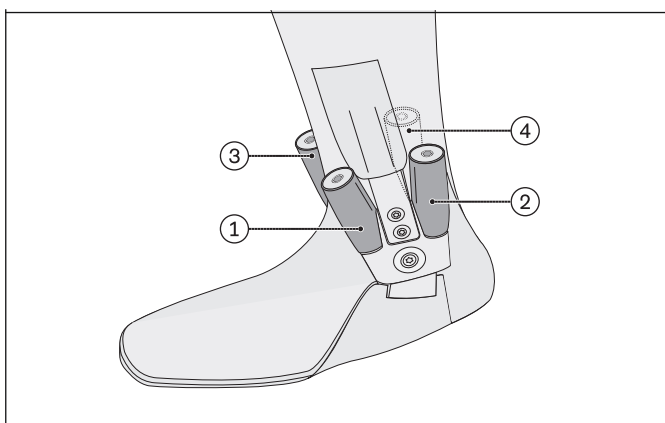


Take note of the knee extension at the end of the terminal stance phase.
Readjust the springs if necessary.

3.11 Adjusting the Reaction Module in a bilateral orthosis

When using multiple Reaction Modules in a bilateral orthosis, note the adjustment order. The stops and spring tension of the Reaction Modules that face each other medially and laterally must be adjusted equally. The identical adjustment of Reaction Modules 1 and 3 as well as 2 and 4 prevents deformation and damage to the orthosis.

Adjusting dorsiflexion and plantar flexion



Follow the steps described in "Installing the Reaction Module" and "Reaction Module – static alignment". **The stops of the Reaction Modules are set according to the adjustment sequence. If a Reaction Module is not required, the corresponding instructions can be ignored.**

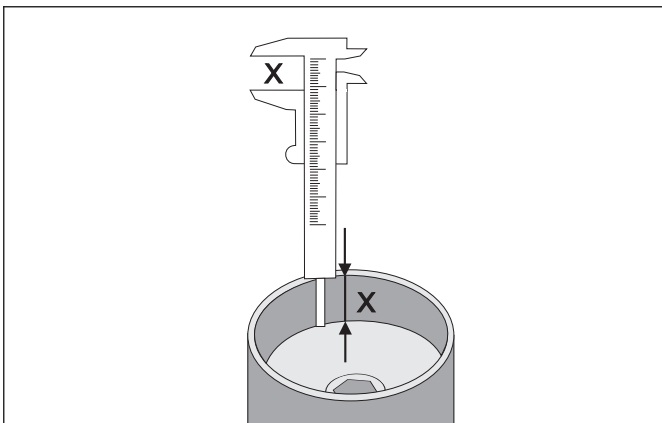
Prerequisite: The orthosis has been applied to the patient.

Prerequisite: All Reaction Modules are mounted with the spring dummy.

- Adjust the stop of Reaction Module 1 (see page 26).
- Adjust the stop of Reaction Module 2 until the orthotic joint has no more anterior-posterior play.
- Set the desired pretension of the Reaction Spring using the spring bolt.
- Have the patient walk while wearing the orthosis.
- If Reaction Modules 1 and 2 have been adjusted and Reaction Module 3 is to follow: Loosen the spring bolt of Reaction Module 1.

- Adjust the stop of Reaction Module 3. If Reaction Module 1 is present, adjust the stop to be identical to Reaction Module 1.
- Now retighten the previously loosened spring bolt of Reaction Module 1.
- If Reaction Module 4 is to be adjusted: Loosen the spring bolt of Reaction Module 2.
- Adjust the stop of Reaction Module 4 until the orthotic joint has no more anterior-posterior play. If Reaction Module 2 is present, adjust the stop to be identical to Reaction Module 2.
- Now retighten the previously loosened spring bolt of Reaction Module 2.
- If a threaded hole is left unused, secure the hole with a dummy cap.
- If necessary, adjust the settings in the static alignment and repeat the steps.

Adjusting the spring tension



Follow the steps described in "Reaction Module – dynamic alignment".

The spring tension of the Reaction Modules is set according to the following adjustment sequence. If a Reaction Module is not required, the corresponding instructions can be ignored.

Prerequisite: The orthosis has been applied to the patient.

Prerequisite: All Reaction Modules are mounted with the Reaction Springs.

- Adjust the spring tension of the spring bolt of Reaction Module 1.
- Adjust the spring tension of the spring bolt of Reaction Module 2.
- Measure and record the screw-in depth of the spring bolt in the cover of Reaction Modules 1 and 2 by means of callipers.
- Adjust the spring tension of the spring bolt of Reaction Module 3. If Reaction Module 1 is mounted, transfer the measurement value from Reaction Module 1 to Reaction Module 3.
- Adjust the spring tension of the spring bolt of Reaction Module 4. If Reaction Module 2 is mounted, transfer the measurement value from Reaction Module 2 to Reaction Module 4.
- If a threaded hole is left unused, secure the hole with a dummy cap.
- Have the patient walk while wearing the orthosis. Readjust the springs if necessary, observing the adjustment sequence.

